

CLAIMS USA

31. (New) A flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs, having a central body with a trapezoid shape with four arms, in which may be distinguished:

- a front portion (A) corresponding to the smaller base of the trapezium, from the ends of which branch off two arms (E);
- a central portion (B) corresponding to the central part of the trapezium;
- a rear portion (D) corresponding to the larger base of the trapezium, from the ends of which branch off two arms (F) diverging from each other and parallel to the sides of the trapezium;

characterised in that the said two arms (E) branch off from the front portion (A) in opposite directions and are coaxial with each other and parallel to said smaller base; and the said central portion (B) has a central hole (U) from which starts a cleft (H).

32. (New) The device according to claim 1, wherein said cleft (H) longitudinally cuts the rear portion (D) of said central body.

33. (New) The device according to claim 1, wherein said cleft (H) longitudinally cuts the front portion (A) of said central body.

34. (New) The device according to claim 1, wherein said cleft (H) longitudinally cuts both the front portion (A) and the rear portion (D) of said central body.

35. (New) The device according to claim 1, wherein said cleft (H) transversely cuts the right central portion of said central body.

36. (New) The device according to claim 1, wherein said cleft (H) transversely cuts the left central portion of said central body.

37. (New) The device according to claim 1, wherein said material with a reticular or laminar structure is selected from the group consisting of materials of organic origin and materials of a synthetic nature.

38. (New) The device according to claim 7, wherein said material of organic origin is selected from the group consisting of membrane of bovine

pericardium, human fascia lata, acellular matrix of pig collagen, and submucosa of pig small intestine.

39. (New) The device according to claim 8, wherein said membrane of bovine pericardium is treated with glutaraldehyde and heparin.

40. (New) The device according to claim 7, wherein said material of a synthetic nature is selected from materials based on single-filament polypropylene.

41. (New) The device according to claim 7, wherein said material of synthetic origin is a mixture of polypropylene and polyglactin.

42. (New) The device according to claim 7, wherein said material has holes having diameter comprised between 0.01 cm and 0.05 cm, at a distance from each other of between 0.06 and 0.1.

43. (New) The device according to claim 7, wherein said material has holes having diameter of 0.03 cm, at a distance from each other of 0.08.

44. (New) The device according to claim 1, wherein:

- the length a-a of the front arms is between 8.0 and 15 cm;
- the length b-b of the front portion is between 2.5 and 6.0 cm;
- the length c-c of the front portion is between 3.0 and 6.0 cm;
- the width b-c of the front arms is between 1.0 and 3.0 cm;
- the length d-y of the front portion is between 2.5 and 6.5 cm;
- the total length d-z of the device is between 4 and 8 cm;
- the length e-f of the rear portion is between 1.8 and 4.0 cm;
- the distance h-h between the rear arms is between 1.5 and 7.0 cm;
- the distance g-g between the rear arms is between 4.9 and 10 cm;
- the distance i-i between the rear arms is between 4.5 and 10.5 cm;
- the length h-i of the rear arms is between 1 and 3 cm.

45. (New) The device according to claim 14, wherein:

- the length a-a of the front arms is 10 cm;
- the length b-b of the front portion is 3.8 cm;
- the length c-c of the front portion is 3.8 cm;
- the width b-c of the front arms is 2.0 cm;
- the length d-y of the front portion is 4.0 cm;
- the total length d-z of the device is 6 cm;

- the length e-f of the rear portion is 2.7 cm;
- the distance h-h between the rear arms is 5.0 cm for patients with a large body size and 3.5 cm for patients with a small size;
- the distance g-g between the rear arms is 8.0 cm for patients with a large body size and 6.9 cm for patients with a small size;
- the distance i-i between the rear arms is 8.5 cm for patients with a large body size and 6.5 cm for patients with a small size;
- the length h-i of the rear arms is 1.5 cm.

46. (New) The device according to claim 1, wherein:

- the length a-a of the front arms is between 8.0 and 15 cm;
- the length b-b of the front portion is between 2.5 and 6.0 cm;
- the length c-c of the front portion is between 3.0 and 6.0 cm;
- the width b-c of the front arms is between 1.0 and 3.0 cm;
- the length d-y of the front portion is between 2.5 and 6.5 cm;
- the total length d-z of the device is between 11 and 15 cm;
- the distance y-x in the central hole U is between 0.6 and 1.6 cm;
- the distance x-e in the central hole U, the same as or different from the distance y-x, is between 0.6 and 1.6 cm;
- the length e-f of the rear portion is between 1.8 and 4.0 cm;
- the distance h-h between the rear arms is between 1.5 and 7.0 cm;
- the distance g-g between the rear arms is between 4.9 and 10 cm;
- the distance i-i between the rear arms is between 4.5 and 10.5 cm;
- the length h-i of the rear arms is between 2.5 and 6.5 cm.

47. (New) The device according to claim 16, wherein:

- the length a-a of the front arms is 10 cm;
- the length b-b of the front portion is 3.8 cm;
- the length c-c of the front portion is 3.8 cm;
- the width b-c of the front arms is 2.0 cm;
- the length d-y of the front portion is 4.0 cm;
- the total length d-z of the device is 12 cm;
- the distance y-x in the central hole U is 1.1 cm;
- the distance x-e in the central hole U is 1.1 cm;

- the length e-f of the rear portion is 2.3 cm;
- the distance h-h between the rear arms is 5.0 cm for patients with a large body size and 3.5 cm for patients with a small size;
- the distance g-g between the rear arms is 7.6 cm for patients with a large body size and 6.0 cm for patients with a small size;
- the distance i-i between the rear arms is 8.5 cm for patients with a large body size and 6.5 cm for patients with a small size;
- the length h-i of the rear arms is 4.5 cm.

48. (New) Method for surgically implanting the flat implantable device as described in claim 1 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

49. (New) Method for surgically implanting the flat implantable device as described in claim 2 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

50. (New) Method for surgically implanting the flat implantable device as described in claim 3 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

51. (New) Method for surgically implanting the flat implantable device as described in claim 4 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina,

comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

52. (New) Method for surgically implanting the flat implantable device as described in claim 5 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

53. (New) Method for surgically implanting the flat implantable device as described in claim 6 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopic surgery, and mini-invasive surgery.

54. (New) Method according to claim 18, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

55. (New) Method according to claim 24, wherein, when the said device is inserted into the vaginal cavity of the patient by means of "tension free" vaginal surgery, the said device is positioned inside the vaginal cavity without fixing it, but only making dissections in the tendinous arch of the levator ani which guarantee the positioning of the front arms of the said device.

56. (New) Method according to claim 18, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two rear arms or the two front arms of the said device in which the cleft extends longitudinally from the central hole respectively on the right and on the left on the said opened tendineous arch; passing respectively the two front arms or rear arms by the sides of the neck of the uterus, one on the right and one on the left until the central part of the said device surrounds the neck of the uterus; rejoining the right and the left half of respectively the front or the rear portion of the device in the centre with two stitches; and bilaterally fixing the front arms or the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

57. (New) Method according to claim 19, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing first one half of the said device through the two front and rear arms and then the other half respectively to the opened tendineous arch and to the sacrospinous ligament or to the iliococcygeal muscle; rejoining the two halves already fixed both at the front and at the rear on the front portion and on the rear portion, taking care to position the neck of the uterus in the central hole.

58. (New) Method according to claim 20, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing first one half of the said device through the two front and rear arms and then the other half respectively to the opened

tendineous arch and to the sacrospinous ligament or to the iliococcygeal muscle; rejoining the two halves already fixed both at the front and at the rear on the front portion and on the rear portion, taking care to position the neck of the uterus in the central hole.

59. (New) Method according to claim 21, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two rear arms or the two front arms of the said device in which the cleft transversely cuts respectively the right or the left central portion of said central body on the said opened tendineous arch; passing respectively the two front arms or rear arms by the sides of the neck of the uterus, respectively both on the left or on the right until the central part of the said device surrounds the neck of the uterus; rejoining the said cleft in the centre with two stitches; and bilaterally fixing the front arms or the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

60. (New) Method for surgically implanting the flat implantable device as described in claim 14 in a patient suffering of a partial prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

61. (New) Method according to claim 30, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the cervix; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the neck of the uterus.